

REMARKS

In response to the Office Action mailed February 9 2005, Applicants respectfully request reconsideration. To further the prosecution of this Application, the Applicant submits the following remarks, has amended claims, has cancelled claims, and has added new claims. In addition, a telephone discussion was conducted with the Examiner and the claims as now presented are believed to be in allowable condition.

Claims 1, 2, 5-10, 12-18, 20-23, 25-29, 32-35, and 37-40 were pending in this application. Claims 1, 10, 20, 21, 28, 38, 42 and 43 are independent claims and the remaining claims are dependent claims. Claim 39 has been cancelled. Claims 41, 42 and 43 have been added. Claims 1, 2, 5-10, 12-18, 20-23, 25-29, 32-35, 37, 38, 40, and 41-43 are now pending in this application.

Claims 1, 2, 5-10, 12-18, 20-23, 25-29, 33, 35, and 37-40 have been rejected. Claims 32 and 34 have been objected to as being dependent upon a rejected base claim but were deemed allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections

Claims 10, 12, 13, 20-23, 25-29, 33, and 37-40 are rejected under 35 U.S.C. §102(b) as being anticipated by being anticipated by U.S. Patent No. 5,991,728 (DeBusk, et al.), hereinafter DeBusk. Claims 10, and 14-18, are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,737,539 to Edelson, et al., hereinafter Edelson. Claims 1-2, 5-9, and 35 are rejected under 35 U.S.C. §103(a) as being unpatentable over DeBusk or Edelson in view of the Applicant's admission of obviousness. The Applicant respectfully disagrees with these contentions and asserts that the present claims, as amended, are not anticipated by any disclosure in the DeBusk or Edelson references, either alone or in combination.

Examiner Interview

The Applicant would like to thank Examiner Rimell for his time during the Interview conducted on April 5, 2005. During the course of the Interview, Applicant's Attorneys and Examiner Rimell discussed the status of claims 32 and 34. The Examiner indicated that claims 32 and 34 were objected to and contained allowable subject matter. Proposed amendments to claim 1 were also discussed as well as amendments to the other independent claims. The Examiner indicated that the use of a database or processor to store a user name and privilege level, to determine the privilege level of the user and to conditionally display data through an output mechanism in accordance with privilege level was not described in DeBusk or Edelson.

Amendments

Independent claims 1, 10, 20, 21, 28, and 38 have been amended. Claim 1 has been amended to include "an output mechanism coupled to the processor to receive the clinical outcome of the sets of medical information and to output the clinical outcome to the user of the digital data processing system, the processor determining the clinical outcome depending upon the associated relative privilege level of the at least one user, such that the at least one user may depend upon the clinical outcome during the course of the medical study and the clinical outcome presenting a first user having a higher privilege level a first portion of the clinical outcome and presenting a second user having a lower privilege level a second portion of the clinical outcome, the second portion of the clinical outcome different from the first portion of the clinical outcome". Claims 10, 20, 21, and 28 have been amended to include "determining a relative privilege level of the user". Claim 38 has been amended to include "determining a relative privilege level of a user" and has also been amended to include "providing the user access to at least a portion of the clinical outcome based upon the relative privilege level associated with the user" from previously examined, and currently cancelled, claim 39. Support for the amendments is found on page 22, lines 13-27 for example. The amendments do not add new

matter to the application. Additionally, the Applicant has not raised any new issue that would require further searching and consideration since the amendments would not create changes that would require searching in different art areas than those already searched.

Rejections under §102(e)

The Office Action has rejected independent claims 10, 20, 21, 28, and 38 under 35 U.S.C. §102(e) as being anticipated by DeBusk. The Office Action has also rejected independent claim 10 under 35 U.S.C. §102(e) as being anticipated by Edelson.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."¹ "The identical invention must be shown in as complete detail as is contained in the ... claim."²

The Office Action has not established that DeBusk anticipates independent claims 10, 20, 21, 28, and 38 of the present Application because DeBusk does not teach or suggest every element of the Applicant's claims. Furthermore, the Office Action has not established that Edelson anticipates independent claim 10 of the present Application because Edelson does not teach or suggest every element of the Applicant's claims. The Applicants respectfully traverse each of these rejections and request reconsideration. The claims are in allowable condition.

DeBusk relates to a computer implementable method and system for tracking and profiling supply usage at the procedural level in the health-care field.³ DeBusk indicates that:

"[i]n the current health-care environment, there is increased pressure to track and minimize costs associated with the delivery of health care. One of the major areas of cost any health care facility

¹ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

² *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

³ DeBusk, col. 1, l. 9-11.

is the supplies used during medical procedures. Often, hospitals and clinics utilized procedural packs which are designed to have all of the supplies the surging or other caregiver might need to use during the procedure. However, when these procedural packs are designed to be comprehensive, there can be considerable waste of supplies simply because they are not use during a particular procedure. Conversely, sometimes a supply is used frequently is not included in a procedural packs, thus requiring that hospital or clinic supplied labor be used to keep an inventory of such supplies and make sure that such supplies are delivered to the care site for the procedure.”⁴

DeBusk provides an integrated package for the tracking of anticipated usage and actual usage of supplies, contrary to prior art tracking methods and system.⁵

DeBusk generally relates to a process for tracking of medical supply usage on a procedural level in clinical setting. In DeBusk, a user creates a procedural template that includes a partial list of supplies or resources to be used during a medical procedure. The user creates a recordation form for a given procedure where the recordation form is based upon the procedural template. The recordation form includes at least a partial listing of the anticipated supplies to be used during the procedure. The recordation form is then used to record actual supply or resource usage information based upon the actual usage of supplies or resources during the performing of the procedure. The usage information from the form is saved in a retrievable manner for use in the analysis of supply or resource usage.

The Office Action indicates, with respect to claims 10, 20, and 28, that Fig. 4 of DeBusk illustrates the step of obtaining an identification of a user (e.g., Login) and a privilege level (e.g., password) where each password of each user is definable as a distinct privilege level. The Office Action further indicates that any given user can view any or all portions of a clinical outcome report by merely reading a portion of the report or the entire report. The Office Action also indicates, with respect to claim 12, that a privilege level is associated with a

⁴ DeBusk, col. 6, l. 24-38.

⁵ DeBusk, col. 6, l. 39-41.

display of data (e.g., display of the clinical outcome report). Users who do not have passwords have a lower privilege level and do not view any data output (e.g., as they are unable to log into the system) and users who do have a password have a higher privilege level and can view the data. As characterized by the Office Action, the system of DeBusk provides an “all-or-nothing” output of the data (e.g., a user having a password can access the data and a user not having a password cannot access the data).

DeBusk does not anticipate the Applicant’s independent claims 10 and 20 because DeBusk does not suggest or disclose determining a relative privilege level of the user and, based on the relative privilege level of the user, presenting a first user having a higher privilege level a first portion of the clinical outcome and presenting a second user having a lower privilege level a second portion of the clinical outcome, as claimed by the Applicant. DeBusk merely provides an “all-or-nothing” output of data where a user having a password can access the data and a user not having a password cannot access the data. DeBusk does not compare relative privilege levels of users and present portions of a clinical outcome study based upon the relative privilege level of the users.

For example, as indicated by claims 10 and 20, both a first user and a second user are presented with the clinical outcome data. The portions of clinical outcome data presented to each user, however, differ, as claimed, based on the relative privilege levels of the user. For example, in the case where the first user has a higher privilege level than the second user, the first user is presented with different portions of the clinical outcome data than the second user. However, as indicated in claims 10 and 20, and contrary to the “all-or-nothing” system in DeBusk, the second user, having a lower privilege level than the first user, is presented with a portion of the clinical outcome data (e.g., a different portion of data than viewed by the first user) even with a lower privilege level than the first user.

DeBusk does not anticipate the Applicant’s independent claim 21 because DeBusk does not teach, disclose or suggest determining a relative privilege level

of the user and generating comparison results describing comparisons of the sets of computerized medical study data to produce a medical study profile, wherein content of the medical study profile is produced at a level according to the relative privilege level of the user, as claimed by the Applicant. The content of the medical study profile only contains doctor ranking information when the relative privilege level is sufficiently high enough to allow that user to rank doctors against other doctors and contains ranking of a non-doctor characteristic when the relative privilege level is not sufficiently high enough to allow that user to rank doctors. The claim clearly defines that there can be multiple privilege levels. In contrast, DeBusk, provides an “all-or-nothing” output of data where a user having a password can access the data and a user not having a password cannot access the data. In Applicant’s claim 21, a medical study profile includes content dependent on the relative privilege level of a user. By contrast to the “all-or-nothing” system in DeBusk, users having different relative privilege levels **can receive** a medical study profile. In the present invention as claimed, the content of the medical study profile (e.g., containing doctor ranking information when the relative privilege level is sufficiently high enough to allow that user to rank doctors against other doctors and containing ranking of a non-doctor characteristic when the privilege level is not sufficiently high enough to allow that user to rank doctors), however, depends on the relative privilege level of the user.

DeBusk does not anticipate the Applicant’s independent claim 28 because DeBusk does not suggest or disclose determining a relative privilege level of the user, selecting first and second characteristics common to at least two sets of medical information according to a clinical algorithm to determine a clinical outcome containing privileged information dependent on the relative privilege level of the user, and outputting the clinical outcome based upon the relative privilege level of the user. Again, DeBusk, provides an “all-or-nothing” output of data where a user having a password can access the data and a user not having

a password cannot access the data. In Applicant's claim 28, a clinical outcome contains privileged information dependent on the relative privilege level of the user. By contrast to the "all-or-nothing" system in DeBusk, users having different relative privilege levels **will receive** a clinical outcome. The content of the clinical outcome (e.g., the privileged information of the clinical outcome), however, depends on the relative privilege level of the user.

DeBusk does not anticipate the Applicant's independent claim 38 because DeBusk does not suggest or disclose determining a relative privilege level of a user and providing the user access to at least a portion of a clinical outcome based upon the relative privilege level associated with the user, as claimed by the Applicant. By contrast to the "all-or-nothing" system in DeBusk, users having different relative privilege levels **can gain** access to a clinical outcome. The content (e.g., portion) of the clinical outcome that a user gains access to, however, depends on the relative privilege level of the user.

Because DeBusk does not disclose or suggest all elements of the Applicant's independent claims 10, 20, 21, 28, and 38, claims 10, 20, 21, 28, and 38 should be allowed to issue. Furthermore, claims 12-18 and 37, which depend upon allowable claim 10, claims 22, 23, and 25-27, which depend upon allowable claim 21, claims 29 and 32-34, which depend upon allowable claim 28, and claim 40, which depends upon allowable claim 38 should also be allowed to issue at least for the reasons presented above.

As indicated above, the Office Action has also rejected independent claim 10 under 35 U.S.C. §102(e) as being anticipated by Edelson.

Edelson relates to a computer-implemented prescription management system to assist physicians in prescribing and reviewing drugs.⁶ The prescription management system includes user computers, such as portable personal computers, connected to a host computer where the host computer provides data or data access to the user computers.⁷ The system allows a physician to create

⁶ Edelson, col. 1, l. 13-15.

⁷ Edelson, col. 7, l. 10-18.

an electronic prescription for a patient at a point of patient care. The system allows a physician to generate a prescription having a patient identifier, a prescribed drug, a dosage for the drug, and a patient-condition treatment specification procedure.⁸ By associating a patient condition with the drug prescribed, the physician identifies and records a treatment objective associated with the drug.

With respect to claim 10, the Office Action indicates that Edelson discloses the concept of obtaining an identification of a user and a privilege level by obtaining a password. The Office Action further states that a password is considered to be a higher privilege level and an individual who does not have a password is considered an individual who has a lower privilege level. As characterized by the Office Action, the system of Edelson, similar to DeBusk, provides an “all-or-nothing” output of (or access to) the data (e.g., a user having the password can access the data and a user not having a password cannot access the data).

Edelson, does not anticipate the Applicant’s independent claim 10 because Edelson does not suggest or disclose determining a relative privilege level of the user and, based on the relative privilege level of the user, presenting a first user having a higher privilege level a first portion of the clinical outcome and presenting a second user having a lower privilege level a second portion of the clinical outcome, as claimed by the Applicant. Edelson, like DeBusk, merely provides an “all-or-nothing” output of data where a user having a password can access the data and a user not having a password cannot access the data. Edelson does not compare relative privilege levels of users and present portions of a clinical outcome study based upon the relative privilege level of the users.

Because Edelson does not disclose or suggest all elements of the Applicant’s independent claim 10, claim 10 should be allowed to issue.

⁸ Edelson, col. 4, l. 30-38.

Furthermore, claims 12-18 and 37, which depend upon allowable claim 10, should also be allowed to issue at least for the reasons presented above.

Rejections under §103

The Office Action has rejected independent claim 1 (and dependent claims 2, 5-9, and 35) under 35 U.S.C. §103(a) as being anticipated by DeBusk or Edelson in view of Applicant's admission of obviousness.

In order to establish a *prima facie* case of obviousness, the Office Action must meet three criteria.

"First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."⁹

The Office Action has not established a *prima facie* case of obviousness with respect to independent claim 1 because neither DeBusk nor Edelson, alone or in combination, teach or suggest all of the claim limitations in independent claim 1.

The Applicant's claim 1 relates to a digital data processing system for determining clinical outcomes of medical data. The digital data processing system comprises an input mechanism that receives sets of medical information, a storage mechanism that receives and maintains the sets of medical information, and a processor coupled to the storage mechanism. The processor uses a clinical algorithm to determine a clinical outcome of the medical information. The processor also determines a relative privilege level of a user. The digital data processing system also includes an output mechanism coupled to the processor to receive the clinical outcome of the sets of medical information and to conditionally output the clinical outcome to the user of the digital data processing system, **the processor determining conditional output of the**

⁹ *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

clinical outcome depending upon the associated relative privilege level of the user. The processor presents, on the output mechanism, a first user having a higher privilege level a first portion of the clinical outcome and presents a second user having a lower privilege level a second portion of the clinical outcome, the second portion of the clinical outcome different from the first portion of the clinical outcome.

As recited above, Edelson and DeBusk provide an "all-or-nothing" output of data where a user having a password can access the data and a user not having a password cannot access the data. Neither Edelson nor DeBusk determines relative privilege levels of users and present portions of a clinical outcome study to a user based upon the relative privilege level of the users.

Because neither DeBusk nor Edelson in view of Applicant's admission of obviousness teaches or suggests every element of the Applicant's independent claim 1, the claim is patentable over DeBusk and Edelson in view of Applicant's admission of obviousness and should be allowed to issue. Accordingly, the rejection of these claims should be withdrawn. Claims 2, 5-9, and 35, which depend on claim 1, should also be allowed to issue as depending upon allowable independent claims (i.e., for at least the reasons presented). Reconsideration of the rejection is respectfully requested.

Additionally, it is noted that claims 2, 5-9 and 35 contain limitations not taught, disclosed or suggested in DeBusk or Edelson, alone or in combination. Specifically, claim 35 provides significant detail on different types of users and on how the processor processes a clinical algorithm for a medical director user and a doctor.

Newly Added Claims

Claims 41, 42 and 43 have been added and are believed to be in allowable condition. Claim 41 depends from claim 1. Support for claim 41 is provided within the Specification, for example, on page 22, lines 13-27. Claim 42 is a combination of subject matter from claims 28, 29 and 32, while claim 43 is a

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combination of subject matter from claims 28, 29 and 34. No new matter has been added.

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Conclusion

In view of the foregoing remarks, this Application should be in condition for allowance. A Notice to this affect is respectfully requested. If the Examiner believes, after this Response, that the Application is not in condition for allowance, the Examiner is respectfully requested to call the Applicants' Representative at the number below.

Applicants hereby petition for any extension of time which is required to maintain the pendency of this case. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 50-0901.

If the enclosed papers or fees are considered incomplete, the Patent Office is respectfully requested to contact the undersigned collect at (508) 366-9600, in Westborough, Massachusetts.

Respectfully submitted,



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